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09/872,250	06/01/2001	Gary S. Grubb	AM100058	4735
35139	7590	07/21/2006	EXAMINER	
COZEN O' CONNOR, P. C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/872,250
Filing Date: June 01, 2001
Appellant(s): GRUBB, GARY S.

Michael Putane
1900 Market Street 5th Floor
Philadelphia, PA 11103-3508
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 12, 2006 appealing from the Office action mailed September 14, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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5,552,349

Hodgen et al.

9-1996

Katzung Basic & Clinical Pharmacology, 6th edition, 1995, page 620

Endrikat et al., Contraception, 1997;55:131-137

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Endrikat et al., Hodgen et al. (US Patent 5,552,394) and Katzung, Endrikat et al. in view of Katzung are of record.

Endrikat et al. teaches oral contraceptives with 30mcg Ethinylestradiol has less breakthrough bleeding than that with 20mcg Ethinylestradiol in the first three cycles. Endrikat also teaches that the patterns of the breakthrough pain as highest in the first cycle was due to the fact that the adaptation of the endometrium to the exogenous hormones takes some time (See page 136, col. 1, last paragraph).

Hodgen et al. teaches a method of reducing breakthrough bleeding in the menstrual cycles except for the first cycle employing ultra-low dose of Ethinylestradiol. Hodgen et al. teaches the dose of Ethinylestradiol as 3-35 mcg (See for example the abstract, claims 1-12).

The primary references do not expressly teach the combination of the oral contraceptives packs together in a kit. The primary references do not expressly teach all of the herein claimed progestins.

Katzung teaches the various progestins herein claimed as useful in oral contraceptive.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the oral contraceptives packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ various progestin herein claimed into the oral contraceptives.

One of ordinary skill in the art would have been motivated to combine the oral contraceptives packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. Hodgen's method of reducing breakthrough bleeding has one drawback, which cannot reduce the breakthrough bleeding in the first cycle. Possessing the teachings of Endrikat, one of ordinary skill in the art would reasonably expect to employ a regimen comprising a dose of 30mcg of ethinylestradiol in the first cycle in the Hodgen's method in order to let the endometrium adapt to the exogenous hormones as well as reduce the breakthrough bleeding in the first cycle and thereby improving Hodgen's method.

One of ordinary skill in the art would have been motivated to employ various progestin herein claimed into the oral contraceptives since substituting various known progestin in oral contraceptives would be considered selecting obvious alternatives among known progestins, absent evidence to the contrary.

(10) Response to Argument

Appellant argues unconvincingly in page 11 in the Brief filed May 12, 2006 averring the cited prior arts' failure to provide motivation to combine the teachings of the prior arts. Examiner notes that the motivation to combine the teachings of cited prior arts is provided. Possessing the teachings of both Endrikat and Hodgen, one of ordinary skill in the art would have realized the drawback for Hodgen's ultra low-dose estrogen method of contraceptives and the initial high dose of estrogen would reduce the incidence of unwanted bleeding taught in Endrikat. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to improve the contraceptive regimen for reducing side effects by increasing the initial dosage of estrogen and then subsequently reducing the dose.

Appellant argues unconvincingly in page 11 and 12 in the Brief filed May 12, 2006 averring the cited prior arts' failure to teach the alteration of dosage of estrogen in different cycles. Examiner notes that the basis of the outstanding rejection is not so much on the altering the estrogen dosage; rather, the cited prior arts provide the motivation to improve the Hodgen's method by employing a higher dosage initially to avoid the breakthrough bleeding. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to improve the contraceptive regimen for reducing side effects by increasing the initial dosage of estrogen (suggestion in Endrikat et al.) and then subsequently reducing the dose (employing Hodgen's method).

Appellant's arguments in page 12-13 in the Brief filed May 12, 2006 averring any benefit of initial high dose of estrogen are unconvincing. As discussed above, higher dose of estrogen would be reasonably expect to help the adaptation of the endometrium to the exogenous hormones and thus, decrease the chances of breakthrough bleeding. Such effect is observed in Endrikat et al. When higher dose of estrogen is used, breakthrough bleeding decreases.

Appellant's arguments in page 13-14 in the Brief filed May 12, 2006 averring the cited prior arts' silence in addressing the problem of breakthrough bleeding are unconvincing. Examiner notes that in Hodgen's method of reducing breakthrough bleeding has one drawback, which cannot reduce the breakthrough bleeding in the first cycle. Taking the teachings of Endrikat, one of ordinary skill in the art would reasonably expect to employ a regimen comprising a dose of 30mcg of ethinylestradiol, which is taught in Endrikat, in the first cycle in the Hodgen's method in order to let the endometrium adapt to the exogenous hormones as well as reduce the breakthrough bleeding in the first cycle and thereby improving Hodgen's method.

Appellant's argues in page 14-15 in the Brief filed May 12, 2006 averring the herein claimed method as unconventional to the teachings of the cited prior arts are not convincing. Examiner notes that Endrikat does not discourage the use of relatively high dose of estrogen in the initial phase. In fact, from the teachings of Katzung, 30 μ g of ethinylestradiol is commonly used.

Appellant's argues in page 15 in the Brief filed May 12, 2006 averring hindsight reasoning being employed by the examiner are not convincing. In response to

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appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the motivation to combine the teachings of the cited prior arts is provided by the cited prior arts to improve the method taught in Hodgen. Therefore, the claims are considered properly rejected under 35 USC 103(a).

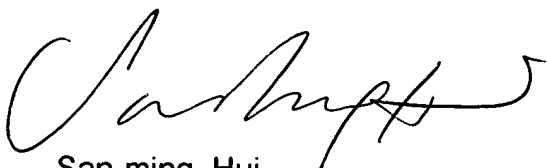
Appellant's arguments in page 16 in the Brief filed May 12, 2006 with regard to long-felt need are not convincing. Examiner notes that there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

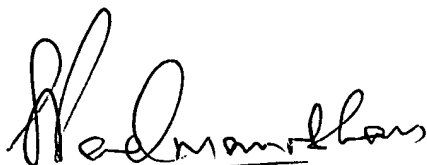
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



San-ming Hui
Primary Examiner
Art Unit 1617

Conferees:



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

SHENGJUN WAI
PRIMARY EXAMINER

